



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,621	07/18/2003	Jan Weber	S63.2-10856-US01	2650
499 7590 05/06/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
KOHARSKI, CHRISTOPHER				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
05/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,621

Applicant(s)

WEBER ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 28, 30-38 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 30-38 and 63-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/2009 has been entered.

Acknowledgements

The Examiner acknowledges the reply filed 2/19/2009 in which claims 27, 32, and 63 were amended and new claims 69-70 were added. Currently claims 27-28, 30-38 and 63-70 are pending for examination in this application.

Claim Objections

Claim 66 is objected to because of the following informalities: Regarding claim 66, the claim should read "...said circumferential elastic bands are located..." in order to maintain proper antecedent basis in the claims as written in other dependant claims such as 67. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 70 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

Art Unit: 3763

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and drawings do not support the first layer being the outer layer and the second layer being the inner layer with the area properties as claimed by Applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-28 and 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Boussignac et al. (USPN5,000,734). Boussignac et al. discloses a body probe assembly.

Regarding claims 27-28 and 63-64, Boussignac et al. discloses a medical balloon (5, Figures 1-2) having a longitudinal axis (along 7) and proximal (near 6) and distal ends (near 4), the balloon formed of radiation cured polymerized composition (col 3, ln 25-50), the balloon (5) connecting to a coaxial shaft (4) at the proximal end thereof and connecting to the same (4) or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal (near 2a) and distal wall (near 2b) portions, respectively,

Art Unit: 3763

wherein the balloon (5) further comprises a lumen (8) offset from the longitudinal axis (along 7) extending through the tapering proximal and distal wall portions, the lumen spaced apart from the coaxial shaft at the proximal end and the coaxial shaft at the distal end (Figures 1-3).

Claim Rejections - 35 USC § 102

Claims 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaffer et al. (USPN5,049,132). Shaffer et al. discloses a balloon catheter for delivering therapy agents.

Regarding claims 32-36, Shaffer et al. discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (44, 16) polymeric material film comprising at least first (44) and second layers (16), each layer having an inner and an outer surface, said first and second layers being in adherent contact (via posts 50) with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (in that the balloon layers (16, 44) are smaller and larger than one another respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

Claim Rejections - 35 USC § 102e

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 36-38, 65, and 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Steadham et al. (USPN7,331,933). Steadham et al. discloses a balloon with compression member.

Regarding claims 32, 36-38, 65, and 69-70, Steadham et al. discloses discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (40, 30, 60, 42) polymeric material film comprising at least first (40) and second layers (30), each layer having an inner and an outer surface, said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state, unstretched band) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (physical size differential between the layers, and pretensioned elastic bands that contract when placed upon the balloon) (col 4, In 40-60) are smaller and larger than one another

Art Unit: 3763

respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

Steadham et al. further discloses a balloon comprising a balloon body (30) having a proximal end (near 46) and a distal end (near 34), and the balloon (30) comprising circumferential elastic bands (40, 42) on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration (col 4, ln 40-60, Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 66-68 are rejected under 35 U.S.C 103(a) as being unpatentable over Steadham et al. (USPN7,331,933) in view of Crocker et al. (USPN6,120,523). Steadham meets the claim limitations as described above

Art Unit: 3763

except for the bands being located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition.

However, Crocker et al. teaches a focalized intraluminal balloon.

Regarding claims 66-68, Crocker et al. teaches a polymeric (cross-linked polyethylene, col 7, ln 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.

At the time of the invention, it would have been obvious to change the placement of the bands and the balloon materials of Steadham in order to gain additional balloon inflation control properties. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Boussignac et al. (USPN5,000,734). Boussignac et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.

Regarding claims 30-31, it would have been obvious to use the medical balloon device as disclosed by Boussignac et al. in combination with a stent delivery catheter or rapid exchange catheter since it well known in the medical

Art Unit: 3763

arts to use stents and exchange catheter to treat body arteries and maintain vessel patency after procedures.

Response to Arguments

Applicant's arguments filed 2/19/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that "...Boussignac et al. fail to disclose any specific polymer material whatsoever, much less forming balloons from radiation cured, polymerized polymer materials as recited in claim 63, nor could Boussignac et al. be found to inherently disclose such materials..." and that "...Radiation cured polyethylene results in a crosslinked polyethylene, very much distinguishable from thermoplastic polyethylene and the resultant product made therefrom would be readily distinguishable. With the radiation cured or crosslinked polymer, bonds will be seen between polymer chains whereas with thermoplastic polyethylene no bonds will exist between the polymer chains, and the resultant physical properties of crosslinked versus noncrosslinked polyethylene will also be different..."

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the Boussignac et al. reference discloses that claimed product by process limitation. Applicant's Representative argues cross linked polyethylene, which is not claimed in the any of the current claims. In this case the resultant product is different; however, this argued composition is not claimed, nor is any specific composition claimed. Further the Boussignac et al.

Art Unit: 3763

reference clearly anticipates the process of radiation curing. The reference discloses (col 3, ln 25-50) that catheter shaft and balloon are made from several suitable medical grade plastics and discloses that the uptakes of exposure to rays can be used to obtain desired strengths and deformabilities. Therefore the reference clearly anticipates using compositions that are capable of being cured via radiation.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, see PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 5/05/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763